EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): patisiran

Procedure No. EMEA/H/C/PSUSA/00010715/201908

Period covered by the PSUR: 10/02/2019 To: 09/08/2019

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for patisiran, the scientific conclusions of CHMP are as follows:

During the reporting interval, the MAH identified one relatively well-described case and one less well-described case of loss of consciousness, both from the US. One further case from Germany was considered to be well-described.

Dizziness and hypotension are labelled as signs of infusion reactions in the SmPC. Syncope is a transient loss of consciousness associated with associated with loss of postural tone and cerebral hypoperfusion and can be associated with orthostatic hypotension which is a decrease in systolic blood pressure of 20mmg Hg or to less than 90mmHg within 3 minutes of standing and can be caused by volume depletion. It is most often associated with movement from the sitting to standing position. An association with syncope is biologically plausible. It is important that HCPs and patients are made aware that hypotension associated with infusion reactions may lead to syncope.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for patisiran the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing patisiran is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.